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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,099	10/31/2003	Dale B. Schenk	015270-008930US	7805

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EXAMINER

HORNING, MICHELLE S

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,099

Applicant(s)

SCHENK ET AL.

Examiner

Michelle Horning

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 15-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is responsive to communication filed 10/16/2006. The status of the claims is as follows: claims 1-14 are under current examination and claims 15-53 are drawn to non-elected inventions.

Applicant's election without traverse of Invention I in the reply filed on 10/16/2006 is acknowledged.

Claim Objections

Claim 14 is objected to because of the following informalities: the claims recites "binds or an alpha-synuclein" instead of the word "to". Appropriate correction is required.

Claim Rejections

35 U.S.C. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Yoshimoto et al (1995) or Wakabayashi et al (1997), in further view of Que et al (1988) and Cleland et al (1995). The limitations to the above claims are as follows: 1) a composition comprising an agent that induces an immunogenic response to alpha-synuclein and an adjuvant; 2) wherein the agent is an alpha-synuclein or a fragment thereof; 3) wherein the agent is linked to a carrier molecule to form a conjugate; 4) wherein the adjuvant is QS21; 5) a composition comprising an agent effective to elicit an immunogenic response against an alpha-synuclein component of an amyloid plaque in a patient; 6) wherein the agent is alpha-synuclein or a immunogenic fragment thereof; 7) wherein the fragment is NAC; and 8) the agent is antibody or fragment thereof that specifically binds to an alpha-synuclein component of an amyloid plaque.

Yoshimoto et al disclose a method in which fragments of NACP, including a fragment consisting of amino acids 61-69 of NACP that corresponds to NAC residues, were used for the preparation of affinity-purified rabbit anti-NACP polyclonal antibody (see Materials and Methods). Wakabayashi et al disclose making an anti-NACP antibody that "was raised by immunizing rabbits with recombinant NACP" (see page 46). Thus, the above references disclose antibodies that specifically bind to alpha-synuclein. This result would be expected to occur *in vivo* because such binding specificity is inherent in the art. Further, Yoshimoto et al disclose preparing an antibody

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against an immunogenic alpha-synuclein fragment that corresponds to NAC. These references do not teach the use of a carrier molecule to form a conjugate or expressly state the use of an adjuvant.

Que et al disclose the effect of carrier selection on immunogenicity of protein conjugates in vaccines (see Abstract). Further, Cleland et al characterize the stability of the adjuvant QS-21 (see whole document). It would have been obvious to one of ordinary skill in the art to combine the teachings above in order to develop a pharmaceutical composition comprising a carrier molecule and QS-21. One would have been motivated to combine the teachings of Que et al and Cleland et al with Yoshimoto et al and Wakabayashi et al in order to increase the immune response to NACP or fragments thereof as well as to ensure a longer shelf life using a stable adjuvant. There would have been a reasonable expectation of success given the success taught by the prior art and both techniques are commonly known and widely used. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 570-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished application is available through Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michelle Horning
Patent Examiner

A handwritten signature in black ink that reads "Bruce Campell". The signature is written in a cursive, flowing style.

**BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**